

## **REMARKS**

Claims 1-20 are pending in the above-identified application. Claim 9 has been cancelled. Claims 1 through 20 were rejected under 35 U.S.C. §102(e) for being anticipated both by Palermo et al. (U.S. Patent 6,228,863 B1) and Kaiko et al. (U.S. Patent 6,277,384 B1). This action was made final. Applicant respectfully traverses the rejection and requests continued examination.

The elements of claim 9 were incorporated into independent claims 1 and 11 to more specifically identify the separate coating of the antagonist. The examiner, in an advisory action dated March 18, 2004, stated that claim 1 does not specifically recite a separate coating for the antagonist.

Claim 1 recites:

“...a pharmaceutical composition in controlled release dosage form...” and

“...an antagonist comprising a dosage form that is coated with a substance that will not release sufficient quantity of said antagonist...”

The coating of the antagonist is further characterized by two qualities. The coating:

“...will not release a sufficient quantity of said antagonist to counteract the effects of the pharmaceutical composition when taken orally...” and

“...will release said sufficient amount if it is chewed or crushed before oral administration.”

These two qualities of the coating of the antagonist distinguish it from the type of form of the pharmaceutical composition, which is a “controlled release dosage form.” Controlled release dosage form is known in the art, and described in the specification of the present application as being a release of a dose over time by either a semi-permeable membrane or other encapsulation with varying levels of a diffusion barrier. In contrast, the coating of the antagonist is claimed to be of a substance that not release a “dose” at all. The coating “will not release a sufficient quantity of antagonist to counteract the effects of the pharmaceutical composition.” This coating substance of the antagonist is clearly different and distinct from a “controlled release dosage form.” Thus, Applicant maintains that the language of claim 1 claims and recites a separate coating for the antagonist from that of the pharmaceutical composition.

The examiner, in an advisory action dated March 18, 2004, stated that claim 1 does not recite any agonist in the formulation, it only recites an antagonist. Claim 1 introduces the antagonist element in reference to the pharmaceutical composition in the following manner: "...an antagonist to said pharmaceutical composition..." The claim term "antagonist" only exists in reference to the claimed term "pharmaceutical composition." When Applicant previously used the term agonist in communications with the examiner, it was intended to mean, and be interchangeable with, the pharmaceutical composition of claim 1.

Independent claim 11 contains similarly claimed elements to claim 1, thus the above remarks apply to claim 11 as well.

Claims 2-8, and 10 depend upon independent claim 1, and are thus patentable for the same reasons given above with respect to claim 1, and more so since they add additional limitations.

Claims 12-20 depend upon independent claim 11, and are thus patentable for the same reasons given above with respect to claim 11, and more so since they add additional limitations.

### **Conclusion**

In summary, Applicant respectfully submits that claims 1-8 and 10-20 as originally submitted and as currently amended, are clearly allowable for the reasons stated herein and therefore request such allowance.

If the Examiner believes a telephone conference with Applicant's attorney would expedite or conclude prosecution of this application, he is cordially invited to contact Applicant's attorney by telephone at the below-listed number.

A request for continued examination and requisite fee are submitted herewith. A request for a 1-month extension of time and requisite fee were previously submitted, extending the response date from January 28, 2004 to February 28, 2004. A request for a 2-month extension of time and fee for extending the time for response in the third month are submitted herewith, extending the response date from February 28, 2004 to April 28,

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2004. The exact amount of the fee is unclear, so the fee for response in the third month is submitted. Please credit any overpayment to deposit account # 15-0490.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Joshua L. Price', with a stylized, flowing script.

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